

FROM W&C LLP 19TH FL.

(MON) 10. 4' 04 16:53/ST. 16:52/NO. 4260454415 P 2

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Applicants request consideration of the patentability of the claimed invention in view of the documents listed on the attached PTO/SB/08A. A copy of each of the documents identified on the attached PTO/SB/08A is submitted as part of this IDS.

REMARKS

A Notice of Allowance was issued in the referenced application on 26 July 2004, and the Issue Fee was paid on 27 July 2004.

As noted by the Examiner in the Notice of Allowability, Applicants have made of record an opposition proceeding before the European Patent Office ("EPO") with respect to the European member, i.e., EP-B-0 652 872 (the "EP patent"), belonging to the same patent family as the referenced application. Specifically, copies of opposition documents, including the written decision upholding the patentability of claims 1-15 of the EP patent, were submitted by an IDS, filed 23 December 2003 and 19 March 2004, respectively.

By this IDS, Applicants respectfully request the Examiner's consideration of the following additional documents which were filed with the EPO and made of record in the opposition proceedings:

1. a letter, dated 1 March 2004, from Dr. Peter Robson, a nonparty to the opposition;
2. an English language translation of an appeal brief, filed 6 July 2004 in German, by ratiopharm GmbH ("ratiopharm"), a party to the opposition; and
3. miscellaneous documents cited by ratiopharm in the appeal brief.

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The first document is a letter from a nonparty to the opposition proceedings. In summary, Dr. Robson expresses his personal opinion that the EPO's decision was incorrect and that claim 1 of the EP patent lacks inventive step in view of DE 40 35 455 ("DE '455") and the relevant EPO case law.

With respect to the appeal brief, ratiopharm argues that the EPO's decision upholding the patentability of claims 1-15 of the EP patent was incorrect. In general, the thrust of the appeal is based on the argument that the EPO's analysis of the closest prior art, i.e., DE '455 and EP 0 124 495 ("EP '495), and the relevant EPO case law was incorrect.

The miscellaneous documents identified in the appeal brief were cited by ratiopharm to supplement other opposition documents already of record which, in ratiopharm's opinion, disclose that it was known that one of two enantiomers frequently displays a different behavior to the other enantiomer or to the racemate. With specific regard to WO 94/24867, this document does not qualify as prior art since its publication date (10 November 1994) is after the priority date (28 May 1993) of the subject application. Furthermore, US 5,888,535 (the "535 patent") to Gray et al. is the U.S. member of the same patent family as the published PCT application WO 94/24867. The '535 patent was cited by Applicants in an IDS and is of record in the subject application.

The referenced application was rigorously examined in view of DE '455 and the U.S. member of EP '495, i.e., US 4,738,974. In fact, the Examiner acknowledged in the "Reason for Allowance" which issued as part of the Notice of Allowability that DE '455 and EP '495 were cited by Applicants in an IDS. Moreover, as a reason for allowance, the Examiner stated that:

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"The chemical compound structures corresponding to EP0124495 (CA 102:137795) and DE4035455 (CA 117:90285) were carefully compared to the instant claims...[T]he instant claims explicitly pointing to the single, nonracemic magnesium salt of (-)-5-methoxy-2-[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]-sulfonyl]-1H-benzimidazole with a purity limitation is neither anticipated nor rendered obvious by the art of record".

Applicants submit that the claimed invention is patentable in view of the newly disclosed documents. The claims of the referenced application are directed to the magnesium salt of (-)-omeprazole characterized by a degree of optical purity. As noted by the Examiner, EP '495 and DE '455 neither disclose nor suggest the claimed invention. Furthermore, Dr. Robson's letter and ratiopharm's appeal represent an interpretation of EP '495 and DE '455 in view of the relevant EPO case law which is not applicable to the patentability of the referenced U.S. application.

For all of the foregoing reasons, Applicants respectfully request the Examiner's consideration of this IDS and issuance of a Notice of Allowance for the reasons of record.

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PAGE 4/64 \* RCVD AT 10/4/2004 4:48:52 PM [Eastern Daylight Time]\* SVR:USPTO-EFXRF-17\* DNIS:8729306\* CSID:2128197583\* DURATION (mm:ss):18:36

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TIME OF TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

The Information Disclosure Statement transmitted herewith is being filed concurrently with a Petition under 37 C.F.R. §1.313(c) and Request for Continued Examination and therefore no separate fee is due. However, authorization is hereby given to charge Account No. 23-1703 for any fee which may be due in connection with this communication.

Dated:

4 October 2004

Respectfully submitted,

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